

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

IN RE: WELSH, Michael J. et al.)	
)	APPEAL NO. _____
SERIAL NO: 10/659,467)	
)	
FOR: NOVEL COMPOSITIONS AND)	
METHODS FOR MODULATION OF)	
THE ACID-SENSING ION CHANNEL)	
(ASIC) FOR THE TREATMENT OF)	
ANXIETY AND DRUG ADDICTION)	
)	REPLY BRIEF
FILED: September 10, 2003)	
)	
GROUP ART UNIT: 1647)	
)	
ATTORNEY DOCKET NO: P05405US01)	
)	
CONF NO.: 6078)	

To the Commissioner of Patents and Trademarks
Mail Code Appeal Brief - Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sirs:

Please enter the following Reply Brief on Appeal into the record, in response to the Examiner's Answer dated August 10, 2010.

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JILL N. LINK

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I. INTRODUCTION

This is a Reply Brief in response to the Examiner's Answer dated August 10, 2010.

II. STATUS OF CLAIMS

Claims 1-4, 24, 25, 30 and 31 are pending. Claim 24 stands rejected by the Examiner under 35 U.S.C. § 112, first paragraph, for lack of enablement. Claims 1-4, 24, 25, 30 and 31 stand rejected under 35 U.S.C. § 112, first paragraph, for written description. The Examiner withdrew the rejection of claims 1-4 under 35 U.S.C. § 112, first paragraph, and claims 25, 30 and 31 under 35 U.S.C. § 112, first paragraph, in the Examiner's Answer dated August 10, 2010. Claims 5-23 and 26-29 stand withdrawn from consideration as they are drawn to non-elected inventions. Claims 1-4, 24, 25, 30 and 31 are currently on appeal.

III. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claim 24 is unpatentable under 35 U.S.C. § 112, first paragraph, for lack of enablement.

B. Whether claims 1-4, 24, 25, 30 and 31 are unpatentable under 35 U.S.C. § 112, first paragraph, for lack of written description.

IV. ARGUMENT

A. **Claim 24 is enabled under 35 U.S.C. § 112, first paragraph and is therefore patentable**

1. Claim 24 Meets the Legal Standard for Enablement

In rejecting claim 24 under 35 U.S.C. § 112, first paragraph, as lacking a specification that fails to provide an enabling disclosure for treating a disease state *associated with increased pH*, according to the claimed invention, the Examiner failed to show that one reasonably skilled in the art would be unable to use the invention based on "the disclosures in the patent coupled with information known in the art without undue experimentation." *U.S. v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). Appellants enabled the claimed invention for a method of treating a disease stated associated with increased pH by administering an ASIC channel antagonist according to both legal precedent and Patent Office practice, as the originally-filed specification directs and enables a person skilled in the art to make the invention commensurate in scope with claim 24. *Id.*; MPEP § 2164.01(c).

2. Claim 24 is Legally Enabled for the Treatment of Diseases Associated with Increased pH by Administering ASIC Antagonists

The Examiner recognized in the Advisory Action dated December 8, 2008 and the Examiner's Answer dated August 10, 2010 that Appellant's amendment after final and Appeal Brief overcame various enablement rejections under 35 U.S.C. § 112, first paragraph. As a result of the Examiner's Answer and the Advisory Action, the Examiner stated that Appellant's invention is enabled for treatment of post-traumatic stress disorder (PTSD) or fear conditioning and CNS disorders characterized by change in extracellular pH in the

amygdale. However, the Examiner maintained the enablement rejection under 35 U.S.C. § 112, first paragraph, with regard to claim 24 for a method of treating a disease state associated with increased pH by administering an ASIC antagonist capable of improving fear responses and a pharmaceutically acceptable carrier.

The Examiner recognizes that Appellant's claims 25 and 30-31 are enabled, as stated on page 7 of the Examiner's Answer dated August 10, 2010. Claim 25 recites that the anxiety condition PTSD is a disease stated associated with increased pH. In addition, claims 30-31 state CNS disorders characterized by changes in extracellular pH in the amygdala include the CNS disorder PTSD. The Examiner states that Appellant's specification, combined with the reference Coryell *et al.* (2007) provides such enablement. However, the Examiner continues to state that Appellants failed to show a nexus among diseases associated with pH change, confirming diseases involve a change in pH, and that the diseases relate to a perturbation of the ASIC receptor.

The Examiner's maintained rejection of claim 24 is inconsistent and should be overturned on Appeal. As the Examiner has already recognized, PTSD is a disease associated with an increase in pH as a result of perturbation of the ASIC receptor. More specifically, the Examiner already recognized that PTSD is a CNS disorder characterized by a change in extracellular pH in the amygdala. Appellants demonstrated that a disease state associated with increased pH includes the anxiety condition PTSD and that exemplary ASIC antagonists that can be administered under the claimed methods, as well as routes of

administration for such methods. As a result, claim 24 presents an invention commensurate in scope with the enabling written description requirement. MPEP § 2164.

Further, Appellant's specification sets forth testing sufficient for a skilled artisan to make and use the invention commensurate in scope with the claimed method of administering to a patient an ASIC antagonist capable of improving fear responses (*i.e.* PTSD in humans), a recognized disease state associated with change in pH. This is further recognized by the Examiner in the withdrawal of the enablement rejection of claims 25 and 30-31. The Examiner's withdrawal of the enablement rejection from the remaining pending claims is further support that the specification is enabled for ASIC antagonists to treat diseases and/or CNS disorder characterized by changes in pH (as set forth in the non-rejected claims). This is coupled with the Examiner's recognition that there is also enablement for a particular embodiment of the invention, the ASIC antagonist agent PcTx (recognized as enabled and allowable by the Examiner in 12/4/08 Advisory Action).

Finally, the specification sets forth for a skilled artisan a variety of *in vivo* testing for a disease state associated with increased pH in mice, the equivalent of PTSD in humans, with and without ASIC receptors. (*See, e.g.*, Specification p. 34, line 18 through p. 36, line 2). In addition, the Examiner previously recognized and appreciated the *in vitro* testing where ASIC were directly antagonized by the manipulation of surrounding pH. As a result, the combination of both *in vivo* and *in vitro* testing demonstrate the relationship between the ASIC receptor and various disease states associated with increased pH sufficient for the enablement requirement set forth under 35 U.S.C. §112, first paragraph. As a result, claim

24 is supported by an enabling specification as required under 35 U.S.C. §112, first paragraph.

B. Claims 1-4, 24, 25, 30 and 31 have adequate written description under 35 U.S.C. § 112, first paragraph and are therefore patentable

1. Claims 1-4, 24, 25, 30 and 31 Meet the Legal Standard for Written Description

In rejecting claims 1-4, 24, 25, 30 and 31 under 35 U.S.C. §112, first paragraph, as lacking written description, the Examiner failed to show that Appellants did not have possession of the subject matter claimed. The Examiner states that Appellants conflate the written description and enablement rejections; however, it is clear from the record and Appellants' specification that each of the separate requirements – written description and enablement – are satisfied by Appellants. Appellants respectfully traverse the Examiner's maintained rejection that the subject matter in claims 1-4, 24, 25, 30 and 31 was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Appellants' specification, in addition to the knowledge and skilled of one in the art at the time the application was filed, provide more than a single ASIC antagonist to be used or identified by a skilled artisan to make and use the claimed invention.

2. Claims 1-4, 24, 25, 30 and 31 are Supported by Sufficient Written Description

Appellants herein present further arguments demonstrating that the Examiner's rejection of claims 1-4, 24, 25, 30 and 31 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is inconsistent with the legal requirements for a written description. The Examiner's maintained rejection of the claims based on Appellants' allegedly insufficient disclosure of compounds that would bind ASIC and antagonize the channel is improper. Appellants were in possession of ASIC antagonists and provided sufficient written description for additional ASIC antagonists to show they were in possession of the claimed invention at the time of filing the present invention.

Appellants described the use of antagonists to be used with ASIC for treatment according to the presently claimed invention, sufficient for meeting the requirements under 35 U.S.C. § 112, first paragraph, as applied to the written description requirement. The specification provides written description for all ASIC antagonists, in addition to the precise antagonists identified in the specification including the PcTx ASIC antagonist referenced by the Examiner. The Examiner disregards Appellants' description of the family of ASIC cation channels gated by reductions in pH (including the relation to amiloride-sensitive epithelial sodium channels (ENaCs) and the degenerin/mec family of ion channels (DEGs)). It is evident that the Examiner does not recognize that the written description providing a particular ASIC antagonist in combination with the distinct characteristics of ASIC clearly demonstrate Appellant's possession of the claimed invention to satisfy the written description requirement.

Appellants' explanation of the ASIC antagonists and the specifics of the ASIC show reduction to practice of the claimed invention, in addition to the particular ASIC antagonist

PcTx. A skilled artisan will recognize based on Appellants' disclosure of ASIC, that the claimed invention was in Appellants' possession, based on the written description of the following: subunits of the DEG/ENaC protein family associating as homomultimers and heteromultimers to form voltage-insensitive channels (Specification p. 13, lines 10-28); individual subunits with two transmembrane domains, intracellular carboxyl- and amino-termini, and a large, cysteine-rich extracellular domain thought to serve as a receptor for extracellular stimuli (Specification p. 13, lines 10-28); and an examples of specific antagonists of the DEG/ENaC channels, including the diuretic amiloride (Specification p. 13, lines 13-16) and PcTx (Specification p. 14, lines 6-10). One skilled in the art finds essential the structure of the channel to which it is antagonizing. Accordingly, Appellants' description of ASIC is further evidence of its possession of the claimed invention.

It is unclear the number of ASIC antagonists the Examiner wishes to see tested *in vitro* and/or *in vivo* in order to satisfy such a heightened level of scrutiny for written description under 35 U.S.C. §112, first paragraph. However, this is not representative of the requisite test for written description. Appellants demonstrated their possession of the invention and reduction to practice at the time of the application by setting forth various forms of antagonists that have been obtained and utilized by those of ordinary skill in the art, for testing ASIC-related conditions and disorders that are commensurate in scope with the claimed invention. As a result, claims 1-4, 24, 25, 30 and 31 are supported by a specification that demonstrates possession of the claimed invention, sufficient to meet the requirements under 35 U.S.C. §112, first paragraph, for written description.

V. **CONCLUSION**

In view of the foregoing, the Examiner's rejections should be reversed as the claims are in a condition for allowability. The decision of the Examiner, therefore, should be reversed and the case allowed.

No fees or extensions of time are believed to be due in connection with this Reply Brief; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "jill n link", written in a cursive style.

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